

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61K 9/00	A1	(11) International Publication Number: WO 98/47484 (43) International Publication Date: 29 October 1998 (29.10.98)
(21) International Application Number: PCT/IB98/00558 (22) International Filing Date: 14 April 1998 (14.04.98) (30) Priority Data: 9707977.6 21 April 1997 (21.04.97) GB (71) Applicant (for all designated States except US): THE PROCTER & GAMBLE COMPANY [US/US]; One Procter & Gamble Plaza, Cincinnati, OH 45202 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): BEALIN-KELLY, Francis, Joseph, David [IE/GB]; 128 Cottimore Avenue, Surrey KT12 2AG (GB). HANKE, Bernhard [DE/DE]; Breslauerstrasse 12, D-65307 Bad Schwalbach (DE). NIENABER, Paul [DE/DE]; Talstrasse 54 a, D-55218 Ingelheim (DE). (74) Agents: REED, T., David et al.; The Procter & Gamble Company, 5299 Spring Grove Avenue, Cincinnati, OH 45217 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: CENTRE FILLED CONFECTIONERY (57) Abstract The invention relates to throat drops comprising from 60 to 95 %, of an edible shell ad from 5 to 40 % of an aqueous filling, by weight of the drop, the filling comprising from 8 to 20 % water, from 50 % to 85 % of a bulk sweetener and suffucient emulsifier to provide a contact angle of from 90 to 120°, the filling having a contact angle of greater than 120° in the absence of the emulsifier. The reduction in contact angle relative to a composition without the emulsifier provides an improved perception of liquidity of the filling.		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

CENTRE FILLED CONFECTIONERY

Field of the Invention

- 5 The present invention relates to liquid centre-filled confectionery, especially liquid centre-filled throat drops, for soothing of irritated throats and nasal passages.

Background of the Invention

Products in the form of cough drops have long been known as vehicles for the delivery of medicaments aimed at soothing sore or irritated throats. Such
10 medicaments include analgesics, antitussives, expectorants, cooling agents such as menthol, and warming agents such as ethanol or gingerol. The medicament can be administered by way of a throat drop or lozenge which releases the active agent upon sucking. Particularly in the case of a volatile active agent, the product can also provide relief from cold symptoms by way of clearing the nasal passages.

- 15 EP-A-431,376, for example, describes hard confections for sustained release treatment of sore throats comprising hydrogenated isomaltulose and an active ingredient which can be an antitussive or antihistamine but can also be a volatile oil such as menthol or eucalyptus. The confection normally contains a further flavouring agent such as lemon, honey or cherry but which can also be menthol or
20 eucalyptus.

A well accepted form of throat drop is a centre-filled throat drop consisting of an edible shell and a liquid centre-filling. The liquid centre provides a pleasant soothing effect on the throat which may be further enhanced by an active agent as described above.

- 25 One of the problems with such throat drops is to provide the optimum degree of liquidity in the centre filling. Typically the edible shell cannot tolerate a high degree of moisture in the filling for reasons of product stability. Levels of moisture in the filling are usually less than 20%. The bulk of the filling usually comprises a bulk sweetener to improve the palatability of the product. These constraints often mean
30 that the viscosity of the filling is rather high, say in excess of 50,000 mPa.s, resulting in a reduction in perception of liquidity of the centre.

US-A-3,894,154 discloses the inclusion of a glycerine in the centre of liquid centre-filled chewing gum for retarding increases in viscosity of the liquid fill portion.

Whilst such an approach is effective, especially within a corn syrup base, it is often not of itself sufficient.

US-A-4,157,402 discloses the use of an emulsifier in the filling of a centre-filled chewing gum to prevent the flavoured liquid filling penetrating into the surrounding gum composition, thus improving the flavour retaining capacity of the chewing gum.

It has now surprisingly been found that the addition of sufficient emulsifier to the liquid filling of a centre-filled hard candy to reduce its contact angle against a gelatine coated plate from more than 120° to a value in the range of 90 to 120°, is sufficient to provide an improvement in the perception of liquidity, and thus throat soothing, even though such addition may result in an increase in viscosity.

It is accordingly an object of this invention to provide centre-filled candy compositions, especially throat drops, with an improved perception of liquidity of the filling.

It is a further object of the invention to provide centre-filled throat drops, with an improved perception of throat soothing.

Summary of the Invention

The present invention relates to a throat drop comprising from 60 to 95%, of a candy shell and from 5 to 40% of an aqueous filling, by weight of the drop, the filling comprising from 8 to 20% water, from 50% to 85% of a bulk sweetener and sufficient emulsifier to provide a contact angle of from 90 to 120°, the filling having a contact angle of greater than 120° in the absence of the emulsifier.

All levels and ratios are by weight, unless otherwise indicated. Percentages are by weight of the filling unless otherwise specified.

Detailed Description of the invention

The throat drops of the present invention comprise from 60 to 95%, preferably from 75 to 85%, of a candy shell and from 5 to 40%, preferably from 15 to 25%, of an aqueous filling, by weight of the drop.

Centre-filled hard candies are described in US-A-4,372,942 and US-A-4,466,983. A suitable sugar base for a hard candy shell comprises from about 30% to about 85% glucose syrup and from about 15% to about 70% sucrose. Alternatively, a sugar-free base can be used for the shell. Suitable sugar-free bases include bulk sweeteners such as isomalt, maltitol and sorbitol. Isomalt and maltitol are preferred. The inner

surface of the shell can also have a separate edible lining to prevent or reduce interaction of the filling with the shell. The edible shell can also further comprise flavours and throat relief agents as described further below.

5 The aqueous filling comprises water at a level of from about 8 to about 20%, more preferably from about 10 to about 15% by weight of the filling. Levels of water higher than about 20% are unsuitable for the production of centre-filled hard candies.

10 The filling further comprises a bulk sweetener, such as a sugar, suitably at a level of from about 50 to 85%, preferably from about 60 to about 75% on a dry solids basis by weight of the filling. A preferred source of the sweetener is high fructose corn syrup which, being commercially available as an 85% active material of which the balance is essentially water, can also provide some, or even all, of the water required. Sugar free compositions comprising a sugar alcohol such as sorbitol can also be used.

15 An essential component of the filling is an emulsifier, present in sufficient quantity to provide a contact angle of from 90 to 120°, the filling having a contact angle of greater than 120° in the absence of the emulsifier. Preferably the filling comprises sufficient emulsifier to provide a contact angle of from 95 to 115°, preferably from 100 to 110°. The 'contact angle', as used herein is the static contact angle of a drop
20 of the filling on a gelatine coated cover slip, measured using a surface tensiometer and optical measuring apparatus (such as those manufactured by Kruss, Germany). The gelatine coated cover slip, prepared by dip coating a glass cover slip in a hot gelatine solution and cooling, is used as a model for the human mucous membrane.

25 The emulsifier should be a food-grade material. Suitable emulsifiers include mono- and di fatty acid glycerides such as those based on soya oil e.g. Imwitor 440 from Huels, acetoglycerides such as Dynacet 211, monoglycerides esterified with citric acid, such as Imwitor 370, and lecithins such as the Topicithin range from Lucas Meyer, Germany. Preferred is soybean lecithin. Suitable levels of the emulsifier are from 0.001 to about 1%, more preferably from about 0.005 to about 0.1% and
30 especially from about 0.01 to about 0.05% by weight of the filling.

An optional but desirable component of the throat drops of the present invention is a throat relief agent. By "throat relief agent" herein is meant any organic compound or mixture of compounds capable of providing relief to a person with a sore or irritated throat or nasal passage. Classes of throat relief agents include, but are not

limited to analgesics, antitussives, expectorants, physiological cooling agents, physiological warming agents and mixture thereof. Preferably the throat relief agent is selected from physiological cooling agents, physiological warming agents and mixtures thereof. Suitable levels of the throat relief agent are from about 0.001 to about 10%, preferably from about 0.01 to about 5%, more preferably from about 0.1 to about 3% by weight of the aqueous composition.

Suitable physiological cooling agents are described in WO 97/06695, incorporated by reference herein. Preferred for use herein are physiological cooling agents selected from the group consisting of menthol, peppermint oil, N-substituted-p-menthane-3-carboxamides, acyclic tertiary and secondary carboxamides, 3-l-menthoxy propan-1,2-diol and mixtures thereof. Particularly preferred for use herein are menthol and menthol containing oils such as peppermint oil.

The carboxamides found most useful are those described in US-A-4,136,163, January 23, 1979 to Watson et al., and US-A-4,230, 688, October 28, 1980 to Rowsell et al. The carboxamides in US-A-4,136,163 are N-substituted-p-menthane-3-carboxamides. N-ethyl-p-menthane-3-carboxamide, commercially available as WS-3 from Wilkinson Sword, is preferred herein. The carboxamides of US-A-4,230,688 are certain acyclic tertiary and secondary carboxamides, of which trimethyl isopropyl butanamide, commercially available as WS-23 from Wilkinson Sword is preferred for use herein.

Preferred physiological warming agents are those selected from the group consisting of vanillyl alcohol n-butyl ether, vanillyl alcohol n-propyl ether, vanillyl alcohol isopropyl ether, vanillyl alcohol isobutyl ether, vanillyl alcohol n-amino ether, vanillyl alcohol isoamyl ether, vanillyl alcohol n-hexyl ether, vanillyl alcohol methyl ether, vanillyl alcohol ethyl ether, gingerol, shogaol, paradol, zingerone, capsaicin, dihydrocapsaicin, nordihydrocapsaicin, homocapsaicin, homodihydrocapsaicin, ethanol, iso-propyl alcohol, iso-amylalcohol, benzyl alcohol, chloroform, eugenol, cinnamon oil, cinnamic aldehyde, and phosphate derivatives thereof. The phosphate derivatives are those described in WO 97/02273, incorporated by reference herein.

The throat drops of the present invention can also comprise from 0.001 to 10% by weight of the filling of a vesicle-forming agent which acts to form vesicles which are dispersed within the filling and encapsulate the throat relief agent. By 'vesicle' is meant an essentially spherical structure comprising a lipid bilayer encapsulating a central core. The vesicles herein can be uni- or multi-lamellar and have a number

average particle size of from about 1 to about 100 μm , more preferably from about 5 to about 50 μm . The particle size can be measured using an optical microscope, such as a Nikon Optiphot 2, linked to an electronic image analysis system such as the Linkam MS100. Measurement can also be made using a graduated graticule in the field of view. EP-A-534,823, which describes anhydrous make-up compositions which can form vesicles on exposure to water gives a comprehensive list of amphiphilic liquids which can be used to form vesicles. Appropriately the emulsifier used herein is a vesicle forming agent. The preferred vesicle forming agent of the present invention is a plant-derived lecithins and, especially, soybean lecithin. Soybean lecithin can act to form vesicles at very low levels. Preferably the vesicle forming agent is present at a level of from about 0.001 to about 1%, more preferably from about 0.005 to about 0.1% and especially from about 0.01 to about 0.05% by weight of the filling. With adequate mixing, in the presence of water and a throat relief agent as described herein, the lecithin forms vesicles which encapsulate the throat relief agent.

It has further been found that the vesicle formation is enhanced by the presence of glycerine, which is preferably present at a level of from about 5 to about 25%, preferably from about 10 to about 20%, more preferably from about 12 to about 18% by weight of the filling. When the filling is a sugar-free base comprising a sugar alcohol, it is preferred that the sugar alcohol is employed in admixture with glycerine, since it has been found that sugar alcohols on their own can suppress vesicle formation.

The aqueous fillings herein can also include a flavouring agent. As used herein, the term 'flavouring agent' means those flavour essences and equivalent synthetic ingredients which are added to the flavour composition for the principal purpose of providing flavour to the confectionery product. It excludes throat relief agents as described above. Flavouring agents well known in the confectionery art can be added to the flavour compositions of the invention. These flavouring agents can be chosen from synthetic flavouring liquid and/or oils derived from plants leaves, flowers, fruits and so forth, and combinations thereof. Representative flavouring liquids include: artificial, natural or synthetic fruit flavours such as lemon, orange, banana, grape, lime, apricot and grapefruit oils and fruit essences including apple, strawberry, cherry, orange, pineapple and so forth; bean and nut derived flavours such as coffee, cocoa, cola, peanut, almond and so forth; and root derive flavours such as licorice. The amount of flavouring agent employed is normally a matter of

preference subject to such factors as flavour type, base type and strength desired. In general, amounts up to about 4% by weight are usable with amounts of from about 0.1% to about 1% being preferred.

5 The aqueous filling can be made by straightforward mixing techniques. The general techniques for manufacturing centre-filled confectionery products can be found in the "Silesia Confiserie Manual No. 3", published by Silesia-Essenzenfabrik Gerhard Hanke K.G., Abt. Fachbücherei.

Suitably, fillings herein have a viscosity in the range of from about 5,000 to about 500,000, preferably from about 20,000 to about 250,000, more preferably from
10 about 50,000 to about 100,000 mPa.s. The viscosity is measured at 25°C at a shear rate of 50s⁻¹ using a Physica Rheolab MC100 rheometer.

Centre-filled throat drops according to the invention can be manufactured by deposit, rope-forming and extrusion processes as known in the art. Extrusion and rope-forming processes are preferred. An example of an extrusion process is
15 described in US-A-5,458,894. An example of an extrusion process is described in US-A-5,002,791.

The following examples are given to illustrate the compositions and uses according to the invention. However, the invention is not limited thereto.

Example 1

20 Liquid, centre-filled throat drops were prepared according to formulae A and B below. The liquid filling was made by adding a premix of the lecithin, colour solution, flavour oils and / or cooling and warming agents to a mixture of the high fructose corn syrup pre-warmed to 82°C. The components were mixed for two minutes and co-extruded with a separately made candy base to produce centre-filled
25 throat drops.

	<u>A</u>	<u>B</u>
Candy casing (80% by wt. of drop)	Wt. %	Wt. %
Sucrose	58.12	49.37
Glucose syrup (80% solids)	41.51	49.37
Peppermint oil	0.17	-
Menthol	0.17	0.08
Lemon oil	-	0.27
Citric acid	-	0.91
	100%	100%

Liquid filling (20% by wt. of drop)		
High fructose corn syrup ¹	84.38	84.306
Glycerine	15.0	15.0
Lecithin	0.02	0.02
Lemon oil	-	0.314
Colour (5% aqueous)	0.32	0.16
Peppermint oil	0.15	-
David Michael Heat ²	0.125	0.20
Vanillin	0.005	-
	100%	100%

¹ 85% sugar solids, the balance being essentially water

² A warming agent available from David Michael & Co., Inc., Philadelphia, USA

- 5 The liquid centre fillings have a contact angle of around 109° but a contact angle of about 126° in the absence of the lecithin. The throat drops deliver a pleasant throat soothing effect and provide an improved perception of liquidity of the filling.

WHAT IS CLAIMED IS:

1. A throat drop comprising from 60 to 95%, of a candy shell and from 5 to 40% of an aqueous filling, by weight of the drop, the filling comprising from 8 to 20% water, from 50% to 85% of a bulk sweetener and sufficient emulsifier to provide a contact angle of from 90 to 120°, the filling having a contact angle of greater than 120° in the absence of the emulsifier.
2. A throat drop according to Claim 1, wherein the filling comprises sufficient emulsifier to provide a contact angle of from 95 to 115°, preferably from 100 to 110°.
3. A throat drop according to Claim 1 or Claim 2 wherein the emulsifier is soybean lecithin.
4. A throat drop according to Claims 1 to 3, wherein the drop comprises from 75 to 85% of the shell and from 15 to 25% of the filling by weight of the drop.
5. A throat drop according to any of Claims 1 to 4, wherein the filling comprises from 10 to 15% water.
6. A throat drop according to any of Claims 1 to 5, wherein the filling comprises from 5 to 25%, preferably from 10 to 20%, more preferably from 12 to 18% glycerine.
7. A throat drop according to any of Claims 1 to 6, wherein the filling comprises from 5 to 80%, preferably from 50 to 75%, sugar.
8. A throat drop according to Claim 7, wherein the sugar is provided by high fructose corn syrup.
9. A throat drop according to any of Claims 1 to 6, wherein the shell comprises a sugar-free base.
10. A throat drop according to Claim 9, wherein the filling comprises a sugar alcohol, preferably in admixture with glycerine.
11. A throat drop according to any of Claims 1 to 10, wherein the filling comprises a throat relief agent selected from physiological cooling agents, physiological warming agents and mixtures thereof.

12. A throat drop according to Claim 11, wherein the filling further comprises from 0.001 to 10% by weight of the filling of a vesicle-forming agent which acts to form vesicles which are dispersed within the filling and encapsulate the throat relief agent.
- 5 13. A throat drop according to any of Claims 1 to 12, wherein the filling has a viscosity in the range of from 5,000 to 500,000, preferably from 20,000 to 250,000, more preferably from 50,000 to 100,000 mPa.s.

INTERNATIONAL SEARCH REPORT

I. National Application No

PCT/IB 98/00558

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61K9/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	ES 2 078 186 A (LABORATORIOS CINFA S. A.) 1 December 1995 see the whole document ----	1-13
A	US 5 578 336 A (WOODROW C. MONTE) 26 November 1996 see the whole document ----	1-13
A	US 4 980 169 A (ALFRED OPPENHEIMER, ET AL.) 25 December 1990 see the whole document ----	1-13
A	WO 94 08551 A (THE PROCTER & GAMBLE COMPANY) 28 April 1994 see the whole document ----	1-13
-/--		



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

13 July 1998

Date of mailing of the international search report

21/07/1998

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Ventura Amat, A

INTERNATIONAL SEARCH REPORT

I. International Application No

PCT/IB 98/00558

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>WO 94 08550 A (THE PROCTER & GAMBLE COMPANY) 28 April 1994 see the whole document -----</p>	1-13

INTERNATIONAL SEARCH REPORT

Information on patent family members

II. International Application No

PCT/IB 98/00558

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
ES 2078186 A	01-12-1995	NONE	
US 5578336 A	26-11-1996	NONE	
US 4980169 A	25-12-1990	CA 2041703 A GB 2244419 A,B JP 4228031 A	04-11-1991 04-12-1991 18-08-1992
WO 9408551 A	28-04-1994	AU 678561 B AU 4930793 A AU 5134893 A EP 0662840 A JP 8502288 T MX 9306295 A MX 9306296 A NZ 256346 A WO 9408550 A	05-06-1997 09-05-1994 09-05-1994 19-07-1995 12-03-1996 29-04-1994 30-06-1994 24-04-1997 28-04-1994
WO 9408550 A	28-04-1994	AU 5134893 A MX 9306296 A AU 678561 B AU 4930793 A EP 0662840 A JP 8502288 T MX 9306295 A NZ 256346 A WO 9408551 A	09-05-1994 30-06-1994 05-06-1997 09-05-1994 19-07-1995 12-03-1996 29-04-1994 24-04-1997 28-04-1994